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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,682	04/22/1998	JACOB STEN PETERSEN	273802002200	6434

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MORRISON & FOERSTER LLP
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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/12/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/064,682

Applicant(s)

PETERSEN, JACOB STEN

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14July2003, 16July2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-26 is/are pending in the application.
- 4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3,5-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The Declaration of Jon Holmgren, pursuant to 37 C.F.R. 1.132, received 16July2003, paper#30, is acknowledged.
2. Applicants' Response to Office Action, received 14July2003, paper#32, is acknowledged.
3. The Declaration of Cecil Czerkinsky, pursuant to 37 C.F.R. 1.132, received 14July2003, paper#33, is acknowledged.
4. Claims 1-3 and 5-26 are pending. Claims 21-26 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.
5. Currently, claims 1-3 and 5-20 are under consideration.

Rejection Maintained

6. The rejection of claims 1-3 and 5-20 under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989) is maintained for reasons of record.

The applicants argue that the data in the instant specification conclusively demonstrates that CTB alone given via a mucosal route has no general tolerogenic effect. Only when CTB and the antigen are administered together is a tolerizing effect seen. The data also indicate that CTB has no effect on immune responses to other antigens if they are not also administered together with CTB.

The examiner has considered applicants' argument, and finds it persuasive concerning only claim 5. However, the remainder of the claims, 1-3 and 6-20 do not require that the inducing agent is the target antigen. Thus, these claims appear to be in contradiction to the argument put forth by applicants concerning the basic requirements for "specific" sustained immunological tolerance. In addition, claim 13 recites that the administration of the mucosal

Art Unit: 1645

binding component can occur not only simultaneously with the inducing agent, but in contradiction to applicants' argument, before or after, administration of the inducing agent.

Applicants argue that the cited reference teaches administration of CTB on or before administration of antigen, 'preferably' by nontransintestinal (mucosal) route, in order to generally suppress the immune system from rejecting the graft. Applicants and the Declarations of Dr. Holmgren and Cr. Czerkinsky agree that the reference does not relate to inducing "specific" sustained immunological tolerance in an individual to a target antigen, as specified in the claims.

The examiner has considered applicants' argument, but does not find it persuasive. As stated *supra*, the remainder of the claims, 1-3 and 6-20 do not require that the inducing agent is the target antigen, therefore, claims 1-3 and 6-20 appear to meet the requirements of the cited references concerning specificity. However, while the 'preferred' route of administration of the cited references may be by a nontransintestinal (mucosal) route, the references do teach mucosal administration as claimed by all of the instant claims.

Thus, the cited references not only provide sufficient guidance/examples, but also sufficient motivation for one of ordinary skill in the art to administer CTB as a mixture with an antigen to result in immunotolerance or immunosuppression of an immune response to said antigen.

Conclusion

7. Claims 1-3 and 5-20 remain rejected.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1645

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. This application contains claims 21-26 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

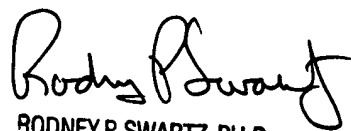
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

Application/Control Number: 09/064,682

Art Unit: 1645

Page 5

A handwritten signature in black ink, appearing to read "Rodney P. Swartz". The signature is fluid and cursive, with the first name "Rodney" and last name "Swartz" clearly distinguishable.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

Art Unit 1645

November 11, 2003